

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH RADIATION SAFETY SECTION IONIZING RADIATION RULES

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PART 14. RADIATION THERAPY INSTALLATIONS

The radiation therapy section is being separated into its own part for improved rule clarity. A majority of this part is new and is based on Part X of the CRCPD's suggested state regulations.

R325.xxx1. Purpose and scope.

Rule xx1. (1) This part establishes requirements for which the registrant is responsible, for the use of therapeutic radiation machines. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these regulations.

(2) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by Rule xxx(number from below).

The wording in subrules 1 and 2 is from the Part X of the Suggested State Regulations for Control of Radiation (SSRCR) of the Conference of Radiation Control Program Directors.

The following section is from Part X of the SSRCR. Statutory language changes may be needed to include the personnel training and qualifications rules.

R325.xxx2. Definitions a to e.

Rule xx2. (1) As used in this part:

(a) "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

(b) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

(c) "Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

(d) "Added filtration" means any filtration which is in addition to the inherent filtration.

(e) "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

(f) "Barrier" see "Protective barrier".

(g) "Beam axis" means the axis of rotation of the beam limiting device.

(h) "Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

(i) "Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

(j) "Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

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(k) "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

(l) "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

(m) "Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than 5 centimeters.

(n) "Detector" (See "Radiation detector").

(o) "Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(p) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

R325.xxx3. Definitions f to l.

Rule xx3. (1) As used in this part:

(a) "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

(b) "Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to Subpart X.6.

(c) "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

(d) "Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. [1 Gy=100 rad].

(e) "Half-value layer (HVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

(f) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(g) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(h) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(i) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(j) "Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

(k) "Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

(l) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(m) "Light field" means the area illuminated by light, simulating the radiation field.

R325.xxx4. Definitions m to p.

Rule xx4. (1) As used in this part:

(a) "mA" means milliampere.

(b) "Megavolt (MV) [mega electron volt (MeV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note: current convention is to use MV for photons and MeV for electrons.]

(c) "Monitor unit (MU)" (See "Dose monitor unit").

(d) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

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(e) "Nominal treatment distance" means:

(i) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(ii) For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(f) "Patient" means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

(g) "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

(h) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

(i) "Phantom" means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(j) "Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" [Medical Physics 18(1): 73-109, Jan/Feb. 1991] and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

(k) "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

(l) "Primary protective barrier" see "Protective barrier".

(m) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(i) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(ii) "Secondary protective barrier" means the material which attenuates stray radiation.

R325.xxx5. Definitions R to s.

Rule xx5. (1) As used in this part:

(a) "Radiation detector" means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(b) "Radiation field" see "Useful beam".

(c) "Radiation head" means the structure from which the useful beam emerges.

(d) "Radiation Therapy Physicist" means an individual qualified in accordance with R325.xxx9.

(e) "Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(f) "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

(g) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

(h) "Secondary protective barrier" see "Protective barrier".

(i) "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

(j) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(k) "Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert. [1 Sv=100 rem].

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(l) "Simulator (radiation therapy simulation system)" means any X-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

(m) "Source" means the region and/or material from which the radiation emanates.

(n) "Source-skin distance (SSD)" see "Target-skin distance".

(o) "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(p) "Stray radiation" means the sum of leakage and scattered radiation.

R325.xxx6. Definitions t to z.

Rule xx6. (1) As used in this part:

(a) "Target" means that part of an X-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(b) "Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the X-ray target and/or electron virtual source to the surface of the irradiated object or patient.

(c) "Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

(d) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(e) "Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

(f) "Tube" means an X-ray tube, unless otherwise specified.

(g) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

(h) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

(i) "Virtual source" means a point from which radiation appears to originate.

(j) "Wedge filter" means a filter which effects continuous change in transmission over all or a part of the useful beam.

(k) "X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.

GENERAL ADMINISTRATIVE REQUIREMENTS

R325.xxx7. Administrative Controls and General Requirements.

Rule xx7. (1) The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of this Part are met in the operation of the therapeutic radiation machine(s).

(2) A therapeutic radiation machine that does not meet the provisions of these regulations shall not be used for irradiation of patients.

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(3) Written safety procedures and rules shall be developed by a Radiation Therapy Physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(4) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who meets the authorized user requirements of this part. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

(5) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of this Part, these individuals are also subject to the requirements of Parts [applicable standards for protection] of these regulations.

(6) After the effective date of these rules, The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

(a) Report of acceptance testing.

(b) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this Part, as well as the name(s) of person(s) who performed such activities.

(c) Records of maintenance and/or modifications performed on the therapeutic radiation machine after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], as well as the name(s) of person(s) who performed such services.

(d) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

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(7) All records required by this Part shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in this Part. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

(8) The facility shall implement a quality management program. The facility may use the quality management programs found in Appendix A.

R325.xxx8. Training for Radiation Therapy Authorized Users.

Rule xx8. (1) The registrant for any therapeutic radiation machine subject to the rules of this Part shall require the authorized user to be a physician who is certified in one of the following:

(a) Radiology or therapeutic radiology by the American Board of Radiology.

(b) Radiation oncology by the American Osteopathic Board of Radiology.

(c) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology".

(d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.

(2) In lieu of meeting the requirements of (1) above, the registrant shall require the authorized user to be a physician who is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.

(3) To satisfy the requirement for instruction in (2) above, the classroom and laboratory training shall include:

(a) Radiation physics and instrumentation.

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(b) Radiation protection.

(c) Mathematics pertaining to the use and measurement of ionization radiation.

(d) Radiation biology.

(4) To satisfy the requirement for supervised work experience in (2) above, training shall be under the supervision of an authorized user and shall include:

(a) Review of the full calibration measurements and periodic quality assurance checks.

(b) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings.

(c) Using administrative controls to prevent misadministrations.

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(e) Checking and using radiation survey meters.

(5) To satisfy the requirement for a period of supervised clinical experience in (2) above, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(a) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(b) Selecting proper dose and how it is to be administered;

(c) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and

(d) Post-administration follow-up and review of case histories.

(6) Notwithstanding the requirements of (1) through (5) above, the registrant for any therapeutic radiation machine subject to [less than 500 kV rules] may also submit the training of the prospective authorized user physician for Agency review on a case-by-case basis.

(7) the physician applying under (6) above shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.

R325.xxx9. Training for Radiation Therapy Physicists.

Rule xx9. (1) The registrant for any therapeutic radiation machine subject to the rules of this Part shall require the Radiation Therapy Physicist to be certified by one of the following:

(a) The American Board of Radiology in therapeutic radiological physics, or roentgen-ray and gamma-ray physics, or x-ray and radium physics, or radiological physics.

(b) The Canadian College of Medical Physics.

(2) In lieu of meeting (1)(b) above, the Radiation Therapy Physicist shall hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full time training in therapeutic radiological physics and also 1 year of full time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in (surveys and calibrations) under the supervision of a Radiation Therapy Physicist during the year of work experience.

(3) Certification pursuant to these rules shall be required 2 years after the effective date of these rules, for all persons currently qualifying as a Radiation Therapy Physicist pursuant to (2) above.

R325.xx10. Qualifications of Operators.

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Rule x10. (1) Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.

(2) The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least 5 years beyond the last date they were permitted to operate a therapeutic radiation machine at that facility.

GENERAL SURVEYS AND DOSIMETRY

R325.xx11. Protection Surveys

Rule x11. (1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with [calibration Rules starting ~ 2 pages from here]. The radiation protection survey shall be performed by, or under the direction of, a Radiation Therapy Physicist or a qualified expert and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Part 4 of these regulations.

(b) Radiation levels in unrestricted areas do not exceed the limits specified in Part 4 of these regulations.

(2) In addition to the requirements of (1) above, a radiation protection survey shall also be performed prior to any subsequent medical use and:

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(a) After making any change in the treatment room shielding.

(b) After making any change in the location of the therapeutic radiation machine within the treatment room.

(c) After relocating the therapeutic radiation machine; or

(d) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the Radiation Therapy Physicist or a qualified expert, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

(4) If the results of the surveys required by (1) or (2) above indicate any radiation levels in excess of the respective limit specified in (1), the registrant shall lock the control in the "OFF" position and not use the unit except under the following conditions:

(a) As may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding.

(b) Until the registrant has received a specific exemption from the Agency.

(5) If the survey required by [xxx(1-4) above] indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Part 4 of these regulations, before beginning the treatment program the registrant shall equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Part 4 of these regulations, perform the required

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survey again, and include in the required report the results of the initial survey, a description of the modification made to comply with the rules, and the results of the second survey.

(6) The registrant for any therapeutic radiation machine subject to this Part shall furnish a copy of the records required in XXX(1-5) above to the Agency within 30 days following completion of the action that initiated the record requirement.

R325.xx12. Survey Instruments.

Rule x12. (1) Each facility location authorized to use a therapeutic radiation machine in accordance with these rules shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with *[calibration of survey instruments]*.

The SSRCR rule above has been moved into this section instead of listing it in both energy class sections to eliminate redundancy.
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R325.xx13. Calibration of Survey Instruments.

The following section is taken from SSRCR, Part X.8

Rule x13. (1) The registrant shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(2) To satisfy the requirements of (1) above, the registrant shall:

(a) Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST)

(b) Calibrate at least two (2) points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale.

(3) To satisfy the requirements of (2) above, the registrant shall:

(a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent.

(b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

(4) The registrant shall retain a record of each calibration required in (1) above for 5 years. The record shall include:

(a) A description of the calibration procedure.

(b) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(5) The registrant may obtain the services of individuals licensed by the Agency, the US Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations that contain information required by (4) above shall be maintained by the registrant.

R325.xx14. Dosimetry Equipment.

Rule x14. (1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration. An Independent survey shall be conducted by a qualified expert or radiation therapy physicist other than the person performing the original survey prior to the equipment being used except as described in xxx(4) above.

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(a) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

(b) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with Rule xxx.(1)[dosimetry] This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in Rule xxx.(1).

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by Rule x14(1 and 2); the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Radiation Therapy Physicist.

GENERAL SHIELDING AND SAFETY DESIGN REQUIREMENTS

R325.xx15. Shielding and Safety Design

General shielding and safety design requirements that apply to ALL radiation therapy rooms are included in this section. Former Rule 315 is modified and moved to this section along with SSRCR Part X.9. Additional shielding design requirements, specific to the energy class of the therapy machine, are included in those sections to follow.

Rule x15. (1) Each therapeutic radiation machine shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with Part 4 [standards for protection] of these regulations.

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(2) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for Agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in part 2, appendix a of these rules.

(3) An enclosure shall be a permanent part of the building or equipment. Portable protective barriers shall not be used for permanent installations.

Moved former Rule 315(1).

(4) The enclosure shall be so constructed that persons may always be able to escape from within.

Moved and clarified former Rule 315(5).

Therapy machine energy distinction changed to reflect SSRCR, Part X for consistency with national standards.

THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 KV

R325.xx16. X-ray equipment.

Rule xxx. (1) When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(a) The leakage air kerma rate, for 5-50 kV systems, measured at any position 5 centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in any one hour.

(b) The leakage air kerma rate, for >50 and <500 kV systems, measured at a distance of 1 meter from the target in any direction shall not exceed 1 cGy (1 rad) in any 1 hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

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(c) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in Rule xxx(1)(a) and (b) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

The definition of "therapeutic type tube housing" has been incorporated in the rule for clarity. The (a), (b), and (c) delineation is from SSRCR X.6a.i-iii.

(2) Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of attenuation as is required of the housing.

(3) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used.

(4) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

Suggested wording for (3) and (4) is from SSRCR, Part X.6c.

(5) The filter system shall be so designed that the filters cannot be accidentally displaced at any possible tube orientation.

Suggested wording is from SSRCR, Part X.6d(i).

(6) The filter system shall be so designed that the air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at 1 meter under any operating conditions.

Suggested wording is from SSRCR, Part X.6d(iii).

(7) Each filter shall be permanently marked with its thickness and material of construction.

Suggested wording is from SSRCR, Part X.6d(iv).

(8) A filter and wedge indication system shall be used on therapy machines using selectable filters or wedges. It shall indicate on the control panel, the presence or absence of a filter or wedge. It shall permit easy recognition of the filter or wedge in place and preclude irradiation unless the selected filter or wedge is in place.

Suggested wording is from SSRCR, Part X.6d(ii) and NCRP No. 102, section 5.1.1(e).

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(9) The x-ray tube shall be so mounted that it cannot turn or slide with respect to the housing aperture.

(10) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

Suggested wording is from SSRCR, Part X.6e(ii).

(11) The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

From SSRCR, Part X.6f.

(12) Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

From SSRCR, Part X.6g.

(13) The control panel, in addition to the displays required in other provisions of Rule xxx, shall have:

(a) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible.

(b) An indication of whether X-rays are being produced.

(c) A means for indicating X-ray tube potential and current.

(d) The means for terminating an exposure at any time.

(e) A locking device which will prevent unauthorized use of the therapeutic radiation machine.

(f) For therapeutic radiation machines manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS?], a positive display of specific filter(s) in the beam.

Suggested wording is from SSRCR, Part X.6i.

(14) When a control panel may energize more than one x-ray tube, it shall be possible to activate only one x-ray tube at any time. There shall be an indication at the control panel identifying which x-ray tube is activated. There shall be an indication at the tube housing assembly when that tube is energized.

Suggested wording is from SSRCR, Part X.6j.

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(15) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(a) A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator.

(b) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.

(c) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

(d) The timer shall permit accurate pre-setting and determination of exposure times as short as 1 second.

(e) The timer shall not permit an exposure if set at zero.

(f) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag.

(g) Timer shall be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

Suggested wording is from SSRCR, Part X.6h.

(17) There shall be a means of determining the central axis target-to-skin distance to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.

Suggested wording is from SSRCR, Part X.6k.

(18) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

Suggested wording is from SSRCR, Part X.6l.

(19) Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel. X-ray therapy units manufactured after

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the effective date of these rules with beryllium window tubes shall be provided with a permanent warning device on the control panel that is activated when no added filtration is present to indicate that the dose rate is very high.

Suggested wording is from SSRCR, Part X.6m.

(20) X-ray equipment shall conform with the appropriate national electrical code in effect during installation. All x-ray machines shall be electrically grounded.

R325.xx17. Additional Facility Design Requirements for 50 kV to 500 kV Machines.

Rule x17 (1) In addition to shielding adequate to meet requirements of X.9, the treatment room shall meet the following design requirements:

(a) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

(b) Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(2) Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(a) All protective barriers shall be fixed except for entrance doors or beam interceptors.

(b) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room.

(c) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

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(d) When any door referred to in (c) above is opened while the X-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

Draft Note: Does this seem like a high exposure rate to allow if the room door is opened?

R325.xx18. Full Calibration Measurements for 50 kV to 500 kV Machines.

Rule x18. (1) Full calibration of a therapeutic radiation machine, operating in the 50 to 500 kV range,
shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist as follows:

(a) Before the first medical use following installation or reinstallation of the therapeutic radiation machine.

(b) At intervals not exceeding 1 year.

(c) Before medical use under the following conditions:

(i) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled.

(ii) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(d) Notwithstanding the requirements of xxx(1)(c) above:

(i) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range.

(ii) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in x18(1)(c)(i) above.

(2) To satisfy the requirement of (1) above, full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

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(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: Measurement results; the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

R325.xx19. Periodic Quality Assurance Checks for 50 kV to 500 kV Machines.

Rule xxx. (1) Periodic quality assurance checks shall be performed on therapeutic radiation machines operating in the 50 kV to 500 kV range.

(2) To satisfy the requirement of (1) above, quality assurance checks shall meet the following requirements:

(a) The registrant shall perform quality assurance checks in accordance with written procedures established by the Radiation Therapy Physicist.

(b) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in Rule xxx(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in Rule xxx(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the Radiation Therapy Physicist shall be investigated and corrected before the system is used for patient irradiation.

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiation Therapy Physicist's quality assurance check procedures, the system shall be recalibrated as required in Rule xxx(1).

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(5) The registrant shall use the dosimetry system described in Rule xxx(1)[dosimetry]. to make the quality assurance check required in Rule xxx(1)[QA].

(6) The registrant shall have the Radiation Therapy Physicist review and sign the results of each radiation output quality assurance check within 1 month of the date that the check was performed.

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to Rule xxx(1) are performed at intervals not to exceed 1 month.

(8) Notwithstanding the requirements of (6) and (7) above, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by (6) and (7) have been performed within the 30 day period immediately prior to said administration.

(9) To satisfy the requirement of (7) above, safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance.

(b) The "BEAM-ON" and termination switches.

(c) Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room.

(d) Viewing systems.

(e) If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by Rule xxx(1) and (7) for 3 years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name;

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model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

R325.xx20. Operating Procedures for 50 kV to 500 kV Machines.

Rule x20. (1) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from therapeutic x-ray equipment pursuant to the requirements of Part 4.

(2) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of Rule xxx [calibration] and Rule xxx [QA] have been met.

(3) Therapeutic radiation machines shall not be left unattended unless secured pursuant to Rule xxx(13)(e)[equipment].

(4) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(5) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV.

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

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(7) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of Part 4 of these regulations.

The following section is taken from the SSRCR, Part X.7 and X.8.

PHOTON THERAPY (> 500 KV) AND ELECTRON THERAPY SYSTEMS (> 500 KEV)

R325.xx21. Equipment.

Leakage Radiation.

Rule x21. (1) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

(2) Except for the area defined in (1) above, the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters.

(3) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

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(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in (1) through (3) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

(5) All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field.

(6) All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(a) A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line 7 centimeters outside the periphery of the useful beam.

(b) A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line 2 centimeters outside the periphery of the useful beam.

(7) Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least 2 tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters.

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(8) Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding 1 square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using 1 centimeter of water equivalent build up material.

Filters and Wedges.

(9) Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.

(10) If the absorbed dose rate information required by Rule xxx(X.7i(below.)) relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools.

(11) Equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS] which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically.

(b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(c) A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use.

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(d) An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

Stray Radiation in the Useful Beam.

(12) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

Beam Monitors.

(13) All therapeutic radiation machines subject to X.7 (>500 kV section) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(14) Equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS] shall be provided with at least 2 independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

(15) Equipment manufactured on or before [INSERT EFFECTIVE DATE OF THESE REGULATIONS] shall be provided with at least 1 radiation detector. This detector shall be incorporated into a useful beam monitoring system.

(16) The detector and the system into which that detector is incorporated shall meet the following requirements:

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(a) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning.

(b) Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated.

(c) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

(d) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], the design of the beam monitoring systems shall ensure that the:

(i) Malfunctioning of one system shall not affect the correct functioning of the other system(s).

(ii) Failure of either system shall terminate irradiation or prevent the initiation of radiation.

(e) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], each display shall:

(i) Maintain a reading until intentionally reset.

(ii) Have only one scale and no electrical or mechanical scale multiplying factors.

(iii) Utilize a design such that increasing dose is displayed by increasing numbers.

(iv) In the event of power failure, the beam monitoring information required in (iii) above, displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

Beam Symmetry.

(17) Bent-beam linear accelerators subject to (>500 kV section) shall be provided with auxiliary device(s) to monitor beam symmetry.

(18) The device(s) referenced in (17) above shall be able to detect field asymmetry greater than 10 percent.

(19) The device(s) referenced in (17) above shall be configured to terminate irradiation if the specifications in (18) above can not be maintained.

Selection and Display of Dose Monitor Units.

(20) Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

(21) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(22) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated.

(23) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

Air Kerma Rate/Absorbed Dose Rate.

(24) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. [The radiation detectors specified in X.7f. may form part of this system.] In addition:.

(a) The dose monitor unit rate shall be displayed at the treatment control panel.

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(b) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant.

(c) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad).

(d) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in (24)(b) and (24)(c) for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Agency.

Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

(25) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

(26) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

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(27) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], an indicator on the control panel shall show which monitoring system has terminated irradiation.

Termination of Irradiation.

(28) It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

Interruption of Irradiation.

(29) If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

Timer.

(30) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(31) A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

(32) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.

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(33) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

Selection of Radiation Type.

(34) Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(a) Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel.

(b) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(c) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected.

(d) An interlock system shall be provided to prevent irradiation with X-rays, except to obtain an image, when electron applicators are fitted.

(e) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted.

(f) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

Selection of Energy.

(35) Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

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(b) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated.

(c) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(d) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy.

(36) Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel.

(b) The mode of operation shall be displayed at the treatment control panel.

(c) An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected.

(d) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel.

(e) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS]:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20 percent from the selected value.

(ii) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected.

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(iii) An interlock shall be provided to prevent motion of more than 5 degrees or 1 cm beyond the selected limits during moving beam radiation therapy.

(iv) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

(v) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

(f) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by (25-27).

(g) For equipment manufactured after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], an interlock system shall be provided to terminate irradiation if movement:

(i) Occurs during stationary beam radiation therapy.

(ii) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

R325.xx22. Additional Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV.

Rule x22. (1) All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) In addition to other requirements specified in this Part, the control panel shall also:

(a) Be located outside the treatment room.

(b) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible.

(c) Provide an indication of whether radiation is being produced.

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(d) Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.

(3) Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with the public dose limits in Part 4 of these regulations, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

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(8) At least 1 emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by Rule x21(28). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

R325.xx23. Radiation Therapy Physicist Support for Therapeutic Radiation Machines Operating above 500 kV.

Rule x23. (1) The services of a Radiation Therapy Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiation Therapy Physicist shall be responsible for:

(a) Full calibration(s) required by R325.xx25, and protection surveys required by

R325.xx11.

(b) Supervision and review of dosimetry.

(c) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use.

(d) Quality assurance, including quality assurance check review required by Rule x26(5).

(e) Consultation with the authorized user in treatment planning, as needed.

(f) Perform calculations/assessments regarding misadministrations.

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(2) If the Radiation Therapy Physicist is not a full-time employee of the registrant, the operating procedures required by R325.xx24 shall also specifically address how the Radiation Therapy Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Radiation Therapy Physicist can be contacted.

R325.xx24. Operating Procedures for Therapeutic Radiation Machines Operating above 500 kV.

Rule x24. (1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of R325.xx11, R325.xx25, and R325.xx26. have been met.

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use.

(4) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

R325.xx25. Acceptance Testing, Commissioning and Full Calibration Measurements for Therapeutic Radiation Machines Operating above 500 kV..

Rule x25. (1) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to R325.xx21 through R325.xx26 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist.

(2) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

(3) Full calibration shall include measurement of all parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45". Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.

(4) The Radiation Therapy Physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

(a) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range.

(b) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected

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mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in Rule x25(4)(a) above.

(5) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: Measurement results; the date of the calibration; the manufacturer's name, model number and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

R325.xx26. Periodic Quality Assurance Checks for Therapeutic Radiation Machines Operating above 500 kV.

Rule x26. (1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to R325.xx21 through R325.xx26 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40".

(2) To satisfy the requirement of (1) above quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40". Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months.

(3) The registrant shall use a dosimetry system that has been inter-compared within the previous 12 months with the dosimetry system described in Rule x14(1) to make the periodic quality assurance checks required in (2) above.

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(4) The registrant shall perform periodic quality assurance checks required by (1) above in accordance with procedures established by the Radiation Therapy Physicist.

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(a) The authorized user and Radiation Therapy Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Radiation Therapy Physicist has determined that all parameters are within their acceptable tolerances.

(b) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or Radiation Therapy Physicist within 3 treatment days.

(c) The Radiation Therapy Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 1 month.

(6) Therapeutic radiation machines subject to R325.xx21 through R325.xx26 shall have safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" performed at intervals not to exceed 1 week.

(7) To satisfy the requirement of (6) above, safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance.

(b) Proper operation of the "BEAM-ON", interrupt and termination switches.

(c) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room.

(d) Viewing systems.

(e) Electrically operated treatment room door(s) from inside and outside the treatment room.

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(f) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(8) The registrant shall promptly repair any system identified in Rule x26(7) that is not operating properly.

(9) The registrant shall maintain a record of each quality assurance check required by Rule x26(1 and 7) for 3 years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

APPENDIX A

R325.xx27 APPENDIX A - QUALITY MANAGEMENT PROGRAM

Rule x27. (1) In addition to the definitions in Rules xx2 through xx6, the following definitions are applicable to a quality management program:

(a) "Misadministration" means the administration of an external beam radiation therapy dose:

(i) Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

(ii) When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(iii) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(iv) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

(b) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic radiation machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique;

(c) "Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

(d) "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

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(2) Scope and Applicability. Each applicant or registrant subject to these rules shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(a) Prior to administration, a written directive is prepared for any external beam radiation therapy dose;

(i) Notwithstanding (a) above, a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

(ii) Notwithstanding (a) above, if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(iii) Notwithstanding (a) above, if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.

(b) Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

(c) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

(d) Each administration is in accordance with the written directive; and

(e) Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(3) Development of Quality Management Program.

(a) Each application for registration subject to these rules shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by Part 2 of these regulations. The registrant shall implement the program upon issuance of a Certificate of Registration by the department;

(b) Each existing registrant subject to these rules shall, within 30 days of [INSERT EFFECTIVE DATE OF THESE REGULATIONS], submit to the Agency a written certification that a quality management program has been implemented.

(4) As a part of the quality management program, the registrant shall:

(a) Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;

(b) Conduct these reviews at intervals not to exceed 12 months;

(c) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of (2) above; and

(d) Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for 3 years.

(5) The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

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- (a) Assembling the relevant facts including the cause;
(b) Identifying what, if any, corrective action is required to prevent recurrence; and
(c) Retaining a record, in an auditable form, for 3 years, of the relevant facts and what corrective action, if any, was taken.

(6) The registrant shall retain:

- (a) Each written directive; and
(b) A record of each administered radiation dose, in an auditable form, for 3 years after the date of administration.

(7) The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

(8) The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:

(a) Notify the department by telephone no later than the next calendar day after discovery of the misadministration;

(b) Submit a written report to the department within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

(c) Notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;

(d) Retain a record of each misadministration for 5 years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and

(e) If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the Agency, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the Agency can be obtained from the registrant;

(9) Aside from the notification requirement, nothing in the quality management program requirements affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.